

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/763,976	HARMS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David Guzo	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 4/2/07.
2. ☒ The allowed claim(s) is/are 2-7, 9-14 and 43.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152), which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application   |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>6/19/07</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date <u>2/14/07</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                  | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                                   |
|   | 9. <input type="checkbox"/> Other _____.  |

### Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Zhibin Ren on 6/19/07.

The application has been amended as follows:

In the **Claims**:

1. (Canceled)
2. (Currently Amended) The system of claim ~~[[1]]~~ 10 wherein the first vector ~~comprises~~ is provided in a host cell.
3. (Currently Amended) The system of claim ~~[[1]]~~ 10 wherein the first vector is selected from ~~a group consisting of~~ a retroviral vector, a plasmid, a cosmid, an adeno-associated viral vector, and an adenoviral vector.
4. (Original) The system of claim 3 wherein the first vector comprises a pseudo-type retroviral vector.

5. (Currently Amended) The system of claim ~~[[1]]~~ 10 wherein the first vector further comprises an RNA export element.

6. (Original) The system of claim 5 wherein the RNA export element comprises a woodchuck mRNA processing enhancer.

7. (Currently Amended) The system of claim ~~[[1]]~~ 10 wherein the first vector comprises a retroviral promoter ~~comprises at least one promoter selected from a group consisting of a bovine leukemia virus promoter, a human T-lymphocyte virus promoter, a simian immunodeficiency virus promoter, and a caprine virus promoter.~~

8. (Canceled)

9. (Currently Amended) The system of Claim ~~8~~ 10 wherein the Tax polypeptide comprises a polypeptide selected from ~~a group consisting of a bovine leukemia virus Tax polypeptide, a human T-lymphocyte virus Tax polypeptide, a simian immunodeficiency virus Tax polypeptide, and a caprine virus Tax polypeptide.~~

10. (Currently Amended) An inducible gene expression system comprising: a first vector comprising at least one retroviral promoter; at least one factor to induce the retroviral promoter, the at least one factor comprising a ~~The system of claim 8 wherein~~

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the Tax polypeptide comprises that comprises amino acids 48-60 of an HIV Tat protein;  
and at least one gene product expressed in proportion to retroviral promoter induction.

11. (Original) The system of claim 10 wherein the Tax polypeptide comprises the  
v amino acids 48-60 of the HIV Tat protein fused to a terminus of said Tax polypeptide.

12. (Original) The system of claim 10 wherein the Tax polypeptide comprises the  
amino acids 48-60 of the HIV Tat protein substituted for the corresponding amino acids  
of said Tax polypeptide.

13. (Currently amended) The system of claim ~~[[1]]~~ 10 wherein the at least one  
factor is provided exogenously.

14. (Currently Amended) The system of claim ~~[[1]]~~ 10 wherein the ~~at least one~~  
~~factor comprises~~ Tax polypeptide that comprises amino acids 48-60 of an HIV Tat  
protein is produced from an encoding nucleic acid sequence provided in a second  
vector.

15-42. (Canceled)

43. (New) The system of claim 10 wherein the first vector comprises a bovine  
leukemia virus promoter and the Tax polypeptide that comprises amino acids 48-60 of

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an HIV Tat protein is a bovine leukemia virus Tax polypeptide that comprises amino acids 48-60 of an HIV Tat protein.

Please substitute the amended Abstract for the as filed Abstract:

### **Abstract**

Inducible gene expression systems and a method thereof. A first inducible gene expression system includes a first vector comprising at least one retroviral promoter and at least one factor to induce the retroviral promoter. At least one gene product is expressed in proportion to retroviral promoter induction. The method includes providing a first vector comprising at least one retroviral promoter and providing at least one factor corresponding to the retroviral promoter. The retroviral promoter is induced with the at least one factor. At least one protein is expressed based on the induction of the retroviral promoter. A second inducing expression system includes a first vector means comprising at least one retroviral promoter, ~~means for inducing~~ an inducer for the retroviral promoter, and ~~means for expressing~~ at least one protein ~~based on the induction of the~~ expressed in proportion to retroviral promoter induction.

The above amendment to the Claims was necessary because the claim amendment filed 4/2/07 was not in compliance with 37 CFR 1.121. Specifically, in claim 10, line 4, the word "that" was newly added by amendment but was not underlined. The amendment filed 4/207 therefore was not entered. The instant examiner's amendment duplicates the amendment of 4/2/07 but with the word "that" in claim 10 underlined.

The amendment to the Abstract was necessary to eliminate legal terminology (i.e. "means for") in the text of the Abstract.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The Declaration filed 1/23/04 claims priority to an application (09/174,221, Title: Method and Testing Instrument for Assessing Skills of an Individual) which appears to be unrelated to the instant case.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
June 21, 2007

  
DAVID GUZO  
PRIMARY EXAMINER